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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

PORTLAND DIVISION

E.S.E. and K.L., individually and on behalf of all others similarly situated, Plaintiffs, v. ALLERGAN, INC. f/k/a INAMED CORPORATION; ALLERGAN USA, INC.; ALLERGAN plc; and DOES 1 through 20, inclusive, Defendants.	Case No. 3:19-cv-01735 CLASS ACTION ALLEGATION COMPLAINT DEMAND FOR JURY TRIAL

CLASS ACTION COMPLAINT

Plaintiffs E.S.E. and K.L. ("Plaintiffs") bring this Class Action Complaint against Defendants ALLERGAN, INC. f/k/a INAMED CORPORATION, ALLERGAN USA, INC., and

ALLERGAN plc (collectively "Defendants" or "Allergan"), on behalf of themselves and all other others similarly situated, and allege as follows:

NATURE OF ACTION

1. Plaintiffs bring this class action against Allergan for manufacturing and selling BIOCELL textured breast implants and tissue expanders that expose women to a higher risk of breast implant-associated anaplastic large cell lymphoma ("BIA-ALCL"), a deadly cancer of the immune system. Although Allergan knew of the increased risks of BIA-ALCL as early as 2011, Allergan failed to warn women considering its implants. Although Allergan has now issued a recall pursuant to a directive by the FDA, it refuses to take full responsibility and refuses to cover the significant costs associated with removal and replacement of the defective devices and medical monitoring, among other damages.

2. Following a request by the FDA, Allergan announced a worldwide recall of all BIOCELL textured breast implants and tissue expanders on July 14, 2019. The models included are:

- **Allergan Natrelle Saline-Filled Breast Implants** (formerly McGhan RTV Saline-Filled Mammary Implant) approved under P990074. The following are the textured styles:
  - Style 163, BIOCELL Textured Shaped Full Height, Full Projection Saline Breast Implants
  - Style 168, BIOCELL Textured Round Moderate Profile Saline Breast Implants, also referred to as 168MP (168 Moderate Profile)
  - Style 363, BIOCELL Textured Shaped Moderate Height, Full Projection Saline Breast Implants, Allergan catalog includes 363LF, or 363 Low Height Full Projection
  - Style 468, BIOCELL Textured Shaped Full Height Moderate Projection Saline Breast Implants

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- **Allergan Natrelle Silicone-Filled Textured Breast Implants** (formerly Inamed Silicone-Filled Breast Implants) approved under P020056. The following are the textured styles:
    - Style 110, BIOCELL Textured Round Moderate Projection Gel Filled Breast Implants
    - Style 115, BIOCELL Textured Round Midrange Projection Gel Filled Breast Implants
    - Style 120, BIOCELL Textured Round High Projection Gel Filled Breast Implants
    - Style TRL, Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants
    - Style TRLP, Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants
    - Style TRM, Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants
    - Style TRF, Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants
    - Style TRX, Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants
    - Style TCL, Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants
    - Style TCLP, Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants
    - Style TCM, Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants
    - Style TCF, Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants
    - Style TCX, Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants
    - Style TSL, Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants
    - Style TSLP, Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants
    - Style TSM, Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants
    - Style TSF, Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants
    - Style TSX, Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants
- **Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast** Implants approved under P040046. The following are the textured styles:
    - Style 410FM
    - Style 410FF

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  - Style 410MM
  - Style 410 MF
  - Style 410 FL
  - Style 410 ML
  - Style 410 LL
  - Style 410 LM
  - Style 410 LF
  - Style 410 FX
  - Style 410 MX
  - Style 410 LX
- **Allergan tissue expanders** for the breast that have BIOCELL texturing originally cleared as:
  - Natrelle 133 Plus Tissue Expander (K143354)
  - Natrelle 133 Tissue Expander with Suture Tabs (K102806)

3. Allergan has refused to pay for the removal of the recalled products or any of the consequences of additional surgery that women who choose removal will have to undergo, or for medical monitoring of the substantially increased risk of BIA-ALCL that all women implanted with the devices have been subjected to.

4. Prior to issuing a request for the recall, the Food and Drug Administration ("FDA") had received reports establishing that BIOCELL implants and expanders were associated with an increase in reported cases of BIA-ALCL: 573 cases of BIA-ALCL worldwide including 33 deaths. Of the 573 known cases of BIA-ALCL, 481 (or about 84%) were attributed to Allergan products, and of the 33 reported deaths, "12 of the 13 patients for which the manufacturer of the implant is known are confirmed to have an Allergan breast implant[.]" According to the FDA, the risk of BIA-ALCL is six times higher with Allergan's textured implants than textured implants from other manufacturers.

5. Amid these revelations and lawsuits like this one, the FDA is now requiring a written warning on the packaging of Allergan's textured breast implants and tissue expanders, to inform consumers of the well-documented risks.

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6. Plaintiffs bring this Action to make Allergan take responsibility for exposing women to a higher risk of BIA-ALCL and to make all women implanted with these defective devices whole by covering all costs associated with the removal, replacement, and recovery, medical monitoring, and all damages arising out of the sale and implanting of these defective devices.

PARTIES

7. Plaintiff E.S.E. is an individual who resides in Beaverton, Oregon.

8. Plaintiff K.L. is an individual who resides in Creswell, Oregon.

9. Given the sensitivity of their claims and the nature of the medical products and services at issue, Plaintiffs are proceeding under a pseudonym in this litigation to protect their privacy. If required by the Court, Plaintiffs will seek permission to use a pseudonym.

10. Defendant ALLERGAN plc is a publicly traded corporation headquartered in Dublin, Ireland. It has administrative headquarters for the United States in New Jersey.

11. Defendant ALLERGAN, INC. f/k/a INAMED CORPORATION, is a wholly owned subsidiary of ALLERGAN plc and is incorporated under the laws of Delaware, with its principal place of business in New Jersey.

12. Defendant ALLERGAN USA, INC. is a wholly owned subsidiary of ALLERGAN plc and is incorporated under the laws of Delaware, with its principal place of business in New Jersey.

13. Plaintiffs are unaware of the true names, capacities, relationship and extent of participation in the conduct alleged herein, of the Defendants sued herein as DOES 1 through 20, but are informed and believe that said Defendants are legally responsible for the wrongful

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conduct alleged herein and therefore sue these Defendants by fictitious names. Plaintiffs will amend this complaint to allege the true names and capacities of the DOES Defendants when ascertained.

JURISDICTION AND VENUE

14. This Court has jurisdiction over Plaintiffs' claims under the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d)(2). The amount in controversy exceeds $5 million exclusive of interest and costs. Some Class Members and Defendants are citizens of different states. There are at least 100 putative Class Members throughout the State of Oregon.

15. Personal jurisdiction and venue are proper in Oregon and within this District because Plaintiffs are residents and citizens of Oregon and within this District; because Plaintiffs' Allergan breast implants were sold and purchased in Oregon and within this District; because Plaintiffs' claims alleged herein arose in substantial part in Oregon and within this District; and because Allergan does substantial business in Oregon and throughout this District.

16. Plaintiffs are informed and believe that each Defendant acted in all respects pertinent to this action as the agent of the other Defendants, carried out a joint scheme, business plan or policy in all respects pertinent hereto, and the acts of each Defendant are legally attributable to the other Defendants.

FACTUAL ALLEGATIONS

I. The Parties

17. On November 16, 2017, Plaintiff E.S.E received Allergan Natrelle Silicone-Filled Textured Breast Implants, Style TSX, Natrelle BIOCELL Textured Soft Touch Silicone-Filled

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Breast Implants. They are included on the list of recalled BIOCELL implants, and she paid approximately $8,500 for the implants and procedure.

18. Plaintiff E.S.E has begun exhibiting symptoms associated with BIA-ALCL including pain, hardening, and swelling of both breasts.

19. On September 21, 2010, Plaintiff K.L. received Allergan Natrelle Silicone-Filled Textured Breast Implants, Style 115, BIOCELL Textured Round Midrange Projection Gel Filled Breast Implants. They are included on the list of recalled BIOCELL implants, and she paid approximately $9,800 for the implants and procedure.

20. Plaintiffs would not have had and/or selected these implants had they known prior to the procedure that it would subject them to the significantly greater risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other fees and procedures to detect and treat BIA-ALCL.

21. Plaintiffs want Allergan to fully pay for the removal of their implants, but Allergan has refused to pay for any surgical costs associated with the recall or medical monitoring of the greatly increased risk of BIA-ALCL.

22. Allergan manufactures and sells BIOCELL breast implants and tissue expanders. Allergan's BIOCELL line of implants are a type of breast implant and tissue expander that are textured to reduce the likelihood of common complications like capsular contracture.

23. The products that were recalled include:

- **Allergan Natrelle Saline-Filled Breast Implants** (formerly McGhan RTV Saline-Filled Mammary Implant) approved under P990074. The following are the textured styles:
    - Style 163, BIOCELL Textured Shaped Full Height, Full Projection Saline Breast Implants

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- Style 168, BIOCELL Textured Round Moderate Profile Saline Breast Implants, also referred to as 168MP (168 Moderate Profile)
- Style 363, BIOCELL Textured Shaped Moderate Height, Full Projection Saline Breast Implants, Allergan catalog includes 363LF, or 363 Low Height Full Projection
- Style 468, BIOCELL Textured Shaped Full Height Moderate Projection Saline Breast Implants

- **Allergan Natrelle Silicone-Filled Textured Breast Implants** (formerly Inamed Silicone-Filled Breast Implants) approved under P020056. The following are the textured styles:
  - Style 110, BIOCELL Textured Round Moderate Projection Gel Filled Breast Implants
  - Style 115, BIOCELL Textured Round Midrange Projection Gel Filled Breast Implants
  - Style 120, BIOCELL Textured Round High Projection Gel Filled Breast Implants
  - Style TRL, Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants
  - Style TRLP, Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants
  - Style TRM, Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants
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  - Style TSF, Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants
  - Style TSX, Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants
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  - Style 410FM
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  - Style 410 MX
  - Style 410 LX
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  - Natrelle 133 Plus Tissue Expander (K143354)
  - Natrelle 133 Tissue Expander with Suture Tabs (K102806)

II. Allergan's Textured Implants Greatly Increase the Risk of Cancer

24. The FDA has confirmed 457 cases of BIA-ALCL in the United States, all linked to textured breast implants. The current lifetime risk of BIA-ALCL runs between 1 in 3,817 and 1 in 30,000. The American Society of Plastic Surgeons estimates the current risk of BIA-ALCL to be between 1 in 2,207 and 1 in 86,029 for women with textured implants.

25. On March 21, 2017, the FDA stated "[a]t this time, most data suggest that BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces rather than those with smooth surfaces." In May 2017, a global analysis of about forty governmental databases showed 363 cases of BIA-ALCL, 258 of which were reported to the FDA.

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26. On March 21, 2018, the FDA released another warning stating that it was aware of 414 total cases of BIA-ALCL. Still, Allergan continued to manufacture and sell the recalled implants and tissue expanders.

27. In December 2018, Allergan textured breast implants lost their European certification and subsequently were suspended from the European and Brazilian markets.

28. In February 2019, the FDA sent a letter to health care providers across the United States warning them about the link between textured breast implants and BIA- ALCL.

29. It was not until July 24, 2019 that Allergan announced a worldwide recall of all BIOCELL textured breast implants and tissue expanders. It waited this long despite knowing for years about the growing data that these devices were unsafe and could cause cancer. And it did not properly disclose this information to patients.

III. Allergan Failed to Disclose the Risks of Its Implants to Patients

30. Patients and their physicians are entitled to know the potential risks of textured implants. The risks of these devices are now public, and because of lawsuits like this one, the FDA is now requiring a written warning on the packaging of Allergan's textured breast implants, to inform consumers of the well-documented risks.

31. Yet, Allergan did not properly make these disclosures before the risks became public and consumers began to sue.

32. Since at least 2011 when it was first reported by the FDA, Allergan knew about the link between its BIOCELL implants and BIA-ALCL.

33. Indeed, since April 1991, the FDA has required breast implant manufacturers to obtain premarket approval for breast implants through the Premarket Approval Applications

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("PMAs") process, which allows the FDA to evaluate the safety and effectiveness of medical devices. This process includes known investigations showing whether or not the device is safe and effective, and other data relevant for evaluating the safety and effectiveness of the device that is known or should reasonably be known to the manufacturer.

34. In 2000, Inamed began conducting a 10-year study to assess the performance and safety of the McGhan Medical RTV Saline-Filled Breast Implant. In 2006, Allergan began long-term studies for its Inamed Silicone-Filled Breast Implants to determine any health concerns including cancer.

35. Allergan is required to file adverse event reports with the FDA, and has the responsibility for timely communicating complete and accurate safety information. It is further obligated to monitor all reasonably available information and clinical experiences.

36. The FDA publishes adverse event reports in a public, searchable database called the Manufacturer and End User Facility Device Experience database or "MAUDE" which is updated monthly.

37. It has been reported that instead of accurately reporting adverse events individually each time an injury occurred, Allergan sought to "bury evidence of ruptures and other injuries by reporting them as routine events that did not require public disclosure." It did this by filing Alternative Summary Reports ("ASR").

38. For nearly two decades, the FDA has allowed manufacturers to submit quarterly spreadsheets through the Alternative Summary Reports Program, summarizing reports of common problems of approved devices. ASRs cannot include severe or unexpected events or

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injuries necessitating remedial action, which should still be disclosed to the public through MAUDE. Yet, it is believed that these incidents were kept hidden in ASRs.

39. In fact, in 2017 when the FDA began implementing more rigorous reporting requirements, there was a dramatic increase in the number of adverse events related to breast implant injuries. It went from 200 a year, to 4,567 in 2017 and 8,242 in the first half of 2018.

40. To increase transparency, on June 21, 2019, the FDA formally ended the Alternative Summary Reporting Program. The FDA said the surge in reports reflected the change in its requirements, rather than a new public health issue.

41. Accurate reporting of adverse events is critical to ensure that the public is adequately and timely notified of potential problems with a medical device. This includes devices manufactured and sold by Allergan.

42. The general public, including physicians and patients, receive information from databases like the MAUDE. Researchers, including those studying connections between breast implants and cancer and other health issues, also use the MAUDE database in their studies of defective medical devices.

43. Upon information and belief, Allergan used the Alternative Summary Reporting Program instead of MAUDE, and as a result, failed to disclose the risks of its medical devices, including those at issue in this litigation.

44. Upon information and belief, Allergan did not report adverse events from its required post-market approval studies that would have suggested the recalled BIOCELL products have caused or contributed to deaths or serious bodily injury.

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45. Allergan continually received new information showing the connection between its textured breast implants and BIA-ALCL and that the risk associated with its BIOCELL breast implants was significantly greater than its competitors. Yet, it failed to properly disclose this information.

46. Allergan failed to comply with the conditions of the PMAs by failing to fulfill its obligations to accurately and promptly report adverse events and continuing to sell the recalled BIOCELL products.

47. Had Allergan complied with its obligations under federal law, the disclosure of the connection between BIOCELL breast implants and BIA-ALCL would have allowed patients including Plaintiffs, and their treating physician to make an informed decision regarding whether to use other implants.

CLASS ACTION ALLEGATIONS

48. Plaintiffs bring this action in their individual capacity and as a class action pursuant to Federal Rule of Civil Procedure 23 on behalf of the following proposed nationwide class and state subclass:

> **Nationwide Class**: All individuals in the United States who implanted BIOCELL saline-filled or silicone-filled breast implants or tissue expanders that have been recalled by the FDA.
>
> **Oregon Subclass**: All individuals who implanted BIOCELL saline-filled or silicone-filled breast implants or tissue expanders that have been recalled by the FDA while in Oregon.

49. Excluded from the Class are Defendants, as well as their officers, employees, agents or affiliates, and any judge who presides over this action, as well as all past and present employees, officers and directors of Defendants. Plaintiffs reserve the right to expand, limit,

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modify, or amend the Class and definitions, including the addition of one or more subclasses, in connection with their motion for class certification, or at any other time, based upon, *inter alia*, changing circumstances and/or new facts obtained during discovery.

50. The Class meets the requirements of Federal Rules of Civil Procedure 23(a) and 23(b)(1), (b)(2), and (b)(3) for all the following reasons.

51. **Numerosity** – Although the exact number of Class members is uncertain, and can only be ascertained through appropriate discovery, the number is great enough such that joinder is impracticable. The disposition of the claims of these Class members in a single action will provide substantial benefits to all parties and the Court. Information concerning the exact size of the putative class is within the possession of Defendants. The parties will be able to identify each member of the Class after Defendants' document production and/or related discovery.

52. **Commonality** – Common questions of fact and law exist as to all Class members and predominate over any questions that affect only individual Class members, including by example only and without limitation, the following:

a. Whether the recalled BIOCELL products significantly increase the risk of developing BIA-ALCL;

b. Whether Allergan knew or should have known that the recalled BIOCELL products significantly increase the risk of developing BIA-ALCL;

c. Whether Allergan was negligent in selling BIOCELL recalled products;

d. Whether Allergan failed to warn consumers regarding the risks of the recalled BIOCELL products;

e. Whether Allergan violated federal standards and requirements for the

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marketing, warning, and reporting of the recalled BIOCELL products;

f. Whether Allergan breached implied warranties connected with the recalled BIOCELL products;

g. Whether Allergan's practices constitute unfair acts or practices under the Unfair Competition Law;

h. Whether Plaintiffs and class members are entitled to equitable relief, including injunctive relief; and

i. Whether Plaintiffs and class members are entitled to damages or other monetary relief, and if so, in what amount.

53. **Typicality –** All of Plaintiffs' claims are typical of the claims of the proposed Class they seek to represent in that: Plaintiffs, like all class members, were implanted with recalled BIOCELL devices and face an increased risk of BIA-ALCL; Plaintiffs' claims arise from the same practice or course of conduct that forms the basis of the Class claims; Plaintiffs' claims are based upon the same legal and remedial theories as the proposed Class and involve similar factual circumstances; there is no antagonism between the interests of Plaintiffs and absent Class members; the injuries that Plaintiffs suffered are similar to the injuries that Class members have suffered.

54. **Adequacy** – Plaintiffs will fairly and adequately represent the Class in that: (1) there is no conflict between Plaintiffs' claims and those of other Class members; (2) Plaintiffs have retained counsel who are skilled and experienced in class actions and who will vigorously prosecute this litigation; (3) Plaintiffs' claims are typical of the claims of Class members.

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55. **Predominance –** The proposed action meets the requirements of Federal Rule of Civil Procedure 23(b)(3) because questions of law and fact common to the Class predominate over any questions which may affect only individual Class members.

56. **Superiority** – A class action is superior to all other methods available for the fair and efficient adjudication of this controversy. Because the amount of each individual class member's claim is small relative to the complexity of the litigation, and given Allergan's financial resources, no class member would be likely to pursue legal redress individually for the violations detailed herein. A class action would also streamline the determination of common claims or issues in this case. Conversely, individual suits would create the potential for inconsistent or contradictory rulings. By contrast, a class action presents fewer management difficulties, allows claims to be heard which would otherwise go unheard, and allows comprehensive supervision by a single court.

57. Injunctive Relief - Class certification is also appropriate under Rule 23(b)(2) because Allergan acted and refused to act on grounds generally applicable to the class, making appropriate final injunctive relief with respect to the class.

FIRST CAUSE OF ACTION
STRICT LIABILITY—FAILURE TO WARN

58. Plaintiffs re-allege and incorporate by reference the allegations contained in the paragraphs above as if fully set forth herein.

59. Allergan manufactured, distributed, and/or sold the BIOCELL breast implants that were implanted in Plaintiffs.

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60. Allergan had a duty to warn Plaintiffs and their physicians about the dangers of the recalled BIOCELL products which it knew, or in the exercise of ordinary care, should have known, at the time the recalled BIOCELL products left Allergan's control.

61. The BIOCELL breast implants had potential risks that were known or knowable considering the scientific and medical knowledge that was generally accepted in the scientific and medical community at the time of the manufacture, distribution, or sale of the implant.

62. Allergan failed to warn Plaintiffs and their physicians about the serious risk of using its recalled BIOCELL products, including the greatly increased risk of BIA-ALCL. At the time Plaintiffs received their implants, Allergan was aware of the clear causal connection between its BIOCELL breast implants but did not disclose this information or warn of the significantly greater risk of BIA-ALCL associated with its implants. Allergan obtained this knowledge from performing extensive decades-long clinical studies, reviewing scientific studies and literature, FDA communications, government reports, and from complaints from consumers, among other sources. Rather than disclose the truth, Allergan, in violation of federal law, attempted to conceal the true facts by not reporting all adverse events to the FDA and by filing ASRs to avoid public reporting on MAUDE.

63. Allergan also failed to warn Plaintiffs and the public by not submitting accurate adverse event reports that patients and physicians rely on to make informed decisions about selecting the type of breast implants.

64. The recalled BIOCELL products were defective and unreasonably dangerous when they left Allergan's possession because they did not contain adequate warnings, including the greatly increased risk of developing BIA-ALCL.

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65. The potential risks presented a substantial danger to Plaintiffs and ordinary consumers when used or misused in an intended or reasonably foreseeable way.

66. Plaintiffs and ordinary consumers would have not recognized the potential for risks.

67. Allergan failed to adequately warn or instruct concerning the potential risks of recalled BIOCELL products.

68. It was foreseeable to Allergan that failure to adequately warn about the risks of its recalled BIOCELL products would cause irreparable harm to those who had the products implanted in their bodies, including the types of emotional distress suffered by Plaintiffs.

69. As a result of Allergan's failures to adequately warn, Plaintiffs were harmed as described herein including physical pain and emotional distress. The lack of sufficient warnings was a substantial factor in causing Plaintiffs' harm. If Plaintiffs and their physicians had been provided with the appropriate warnings regarding the causal connection between BIOCELL implants and BIA-ALCL, they would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL.

70. Allergan's breach of its duty to warn has caused Plaintiffs damages including surgical costs of removal of the products, ongoing medical monitoring, and other medical expenses.

SECOND CAUSE OF ACTION
NEGLIGENCE

71. Plaintiffs re-allege and incorporate by reference the allegations contained in the paragraphs above as if fully set forth herein.

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72. Allergan has a continuing duty to monitor the recalled BIOCELL products to discover and report to the FDA any complaints about product performance and safety. Allergan also has a continuing duty to provide warnings and instructions regarding potential safety hazards associated with the use of its products.

73. Allergan breached these duties by failing to provide timely and adequate reports regarding the safety hazards associated with the recalled BIOCELL products, including the close causal connection to BIA-ALCL. Through numerous adverse reports, consumer complaints, scientific research and literature, internal clinical research, and communications from the FDA and international governmental organizations that Allergan monitored, Allergan was aware of the clear connection between the recalled BIOCELL products and BIA-ALCL, and that its textured breast implants posed a significantly greater risk than competing textured breast implants.

74. Although Allergan knew or should have known that the recalled BIOCELL products posed a serious risk of bodily harm to consumers, Allergan continued to manufacture and market them to consumers and failed to comply with applicable FDA reporting and monitoring requirements.

75. Had Allergan properly and timely reported the adverse events to the FDA as required under federal law, material information regarding the true risk of the recalled BIOCELL products, including the substantially greater risk of developing BIA-ALCL, would have reached Plaintiffs and their treating medical professionals in time to avoid their injuries.

76. Allergan knew or should have known that consumers such as Plaintiffs would foreseeably suffer injury as a result of its failure to exercise ordinary care and comply with FDA reporting and monitoring requirements, including emotional distress.

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77. As a direct result of Allergan's breach of duty, Plaintiffs have suffered harm in an amount to be determined at trial, including severe emotional distress.

THIRD CAUSE OF ACTION
NEGLIGENT RECALL

78. Plaintiffs re-allege and incorporate by reference the allegations contained in the paragraphs above as if fully set forth herein.

79. On July 24, 2019, the FDA requested that Allergan recall its BIOCELL products in the United States. That same day, Allergan voluntarily issued a worldwide recall of BIOCELL products.

80. In issuing a voluntary recall, Allergan assumed duties to Plaintiffs to exercise reasonable care in issuing and implementing the recall.

81. Allergan breached its duties by failing to adequately warn Plaintiffs of the dangers associated with the use of the recalled BIOCELL products and by refusing to pay for the surgical removal of Plaintiffs' implants notwithstanding the clear connection between the recalled BIOCELL products and BIA-ALCL and the continuing risk the implants pose to Plaintiffs' health.

82. As a direct result of Allergan's breach of duty, Plaintiffs have suffered harm in an amount to be determined at trial.

FOURTH CAUSE OF ACTION
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY

83. Plaintiffs incorporates the above allegations by reference.

84. By operations of law, Allergan, as manufacturer of the recalled BIOCELL

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products and as the provider of the Limited Warranty, impliedly warranted to Plaintiffs that the implants they were purchasing were of merchantable quality and safe for their ordinary and intended use in the human body as an aesthetic breast enhancement.

85. Allergan breached the implied warranty of merchantability in connection with the sale and distribution of the recalled BIOCELL products. At the point of sale, the recalled BIOCELL products, while appearing normal, contained latent flaws rendering them unsuitable and unsafe for use in the human body.

86. Had Plaintiffs known the recalled BIOCELL products are unsafe for use in the human body, they would not have purchased them and had them implanted in their bodies.

87. Allergan has refused to provide appropriate warranty relief, as it will not provide surgical fee assistance to patients notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs reasonably expected that their implants would not present a substantial risk of bodily harm at the time of purchase.

88. As a direct and proximate result of Allergan's breach of the implied warranty of merchantability, Plaintiffs have sustained damages in an amount to be determined at trial.

FIFTH CAUSE OF ACTION
VIOLATION OF OREGON'S UNLAWFUL ("UTPA") TRADE PRACTICES ACT, ORS § 646.608, *ET SEQ.*

89. Plaintiffs incorporate the above allegations by reference.

90. Plaintiffs bring this claim on behalf of the Oregon Subclass.

91. Plaintiffs and the Class members are "Persons" within the meaning of ORS 646.605(4).

92. Allergan manufactured, designed, and marketed the recalled textured implants

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and/or tissue expanders in Oregon at all times material, and is in the business of regularly selling and marketing its consumer goods at all times material and is a "person" as defined at ORS 646.605(4).

93. In the course of their business, Allergan, through their agents, employees, and/or subsidiaries, violated the UTPA as detailed above. Specifically, in manufacturing, selling, and designing the recalled textured implants and/or tissue expanders, and in marketing, offering for sale, and selling the defective recalled textured implants and/or tissue expanders, Allergan engaged in unfair or deceptive acts or practices prohibited by ORS § 646.608(1)(e), (i), (j), (k), (p), and (s) including, but not limited to:

a. Selling recalled BIOCELL products that it knew to present a substantially greater risk of developing BIA-ALCL than competing textured breast implants;

b. Concealing the clear connection between its BIOCELL products and BIA-ALCL from the FDA, consumers, and medical professionals;

c. Failing to disclose that the recalled BIOCELL products have a substantially greater risk of developing BIA-ALCL than competing textured breast implants and;

d. Minimizing the scope of the risks associated with using the recalled BIOCELL products in communications with the public.

94. Allergan's failure to disclose and concealment of the clear connection between its BIOCELL products and BIA-ALCL from the FDA, consumers, and medical professionals were material to Plaintiffs and Class members. Had they known the truth, Plaintiffs and Class members would have been able to make an informed decision about using an alternative product

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that did not present such a high risk of BIA-ALCL.

95. Plaintiffs and Class members had no way of discerning that Allergan's representations were false and misleading, or otherwise learning the facts that Allergan had concealed or failed to disclose, because Allergan had exclusive knowledge of the information surrounding the recalled BIOCELL products and did not alert Plaintiffs and Class members to said information prior to purchasing them. Plaintiffs and Class members did not, and could not, unravel Allergan's deception on their own.

96. Allergan had an ongoing duty to Plaintiffs and Class members to refrain from unfair and deceptive practices under the UTPA in the course of their business. Specifically, Allergan owed Plaintiffs and Class members a duty to disclose all the material facts concerning the recalled BIOCELL products because Allergan possessed exclusive knowledge, intentionally concealed it from Plaintiffs and Class members, and/or made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

97. Plaintiffs suffered injury in fact, including lost money or property, as a result of Allergan's unfair acts. Absent Allergan's unfair conduct, Plaintiffs would not have selected Allergan implants.

98. Plaintiffs and Class members suffered ascertainable economic loss and actual damages as a direct and proximate result of Allergan's concealment, misrepresentations, and/or failure to disclose material information.

99. Allergan's violations present a continuing risk to Plaintiffs and Class members, as well as to the general public. Allergan's unlawful acts and practices complained of herein affect the public interest.

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100. Plaintiffs and Class members seek an order enjoining Allergan's unfair and/or deceptive acts or practices, and awarding damages, attorney fees and costs, and any other just and proper relief available under ORS § 646.638.

SIXTH CAUSE OF ACTION
MEDICAL MONITORING

101. Plaintiffs incorporate the above allegations by reference.

102. As a result of exposure to the recalled BIOCELL products, the need for future monitoring is reasonably certain. Allergan's textured implants significantly increase the risk of BIA-ALCL.

103. Medical monitoring is therefore reasonable in order to properly diagnose the symptoms of BIA-ALCL particularly as it can become fatal when not treated in a timely manner.

104. Plaintiffs are therefore entitled to have Allergan pay for the costs of ongoing medical monitoring.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf all others similarly situated, request that the Court enter judgment against Defendants as follows:

A. An order certifying this action as a class action under Federal Rule of Civil Procedure 23, defining the Class as requested herein, appointing the undersigned as Class Counsel, and finding that Plaintiffs are proper representatives of the Class herein;

B. Award Plaintiffs compensatory, restitutionary, rescissory, general, consequential, punitive and/or exemplary damages in an amount to be determined at trial;

C. Enter an injunction against Allergan and its officers, agents, successors,

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employees, representatives, assigns, and any and all persons acting in concert with them, and require them to implement a medical monitoring program for Plaintiffs and class members;

D. Retain jurisdiction over this action to ensure Allergan complies with such a decree;

E. Enter other appropriate equitable relief;

F. Award reasonable attorneys' fees and costs, as provided for by law;

G. Pre-judgment and post-judgment interest as provided by law; and

H. Such other and further relief that the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs, on behalf of themselves and the Class, hereby demand a trial by jury pursuant to Federal Rule of Civil Procedure 38(b) on all claims so triable.

DATED this 30th day of October, 2019.

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